REMARKS

A petition for a one month extension of time has today been filed as a separate paper and a copy is attached hereto.

The non-elected claims are hereby cancelled.

Regarding the examiner's request for a form PTO-1449 at the bottom of page 2 of the office action, please note that the "Supplemental Information Disclosure Statement" filed August 1, 2002 merely served, as a courtesy to the examiner, to submit an English language translation of the "International Preliminary Examination Report." Since no new potential prior art was submitted, no form PTO-1449 could have been submitted.

Responsive to the examiner's objection to the specification, the specification has been corrected to insert Sequence I.D. Nos. Further, a new sequence listing in paper and computer readable forms is submitted herewith, along with a statement under 37 CFR 1.821 - 1.825.

Regarding the objection to claims 21 and 22, the examiner's attention is directed to page 7 of the Preliminary Amendment filed March 4, 2002, a copy of which is appended hereto, along with the mail room receipt for same. The

examiner will note that, as amended March 4, 2002, claims 21 and 22 depend only from claim 1.

Responsive to the rejection for indefiniteness, paragraph 4 of the office action, independent claims 1 and 23 have been amended to clarify that each of receptors I and II is an intact compound or "complex". See, for example, page 17, lines 3 and 5 and page 18, line 9 of applicants' specification. Further, the language "introduced into" in claims 1 and 23 has been replaced by the language "bound to".

What applicants mean by different "bonding" or "bonding capabilities" become clear from a reading of applicants' specification. Fig. 3, for example shows B3 covalently bound to R2 as compound R2-B3 and B2, of the compound L2-B2, forming a biological bond, e.g., complimentary binding, with R2, resulting in the complex L2-B2-R2-B3.

As used in applicants' specification, the terms "bond element" and "anti-bond element" refer to a pair of compounds which bind to each other in some manner, e.g., complementary binding of nucleotide sequences. See, for example, page 20, lines 8-21 and page 38, lines 1-11 of applicants' specification. Thus, the terminology in question is not indefinite when read in light of applicants' specification.

The phrase "the medium", to which the examiner has objected, has been deleted from claims 4 and 23.

Responsive to the examiner's objections to claims 5 and 7 these claims have been amended to clarify that different types of reactivity was the intended meaning. See, for example, page 38, lines 12-16 of applicants' specification.

Claim 6 has been amended to delete the objectionable phrases "or ligands L3" and "the medium". Claim 7 has also been amended to delete "or ligands L3."

Claim 8 has been amended in the interest of clarification as requested by the examiner.

In claim 12, again, the phrase "the ligand L3" has been deleted.

Claim 12 has been amended in light of the teachings at page 14, lines 12-22 and page 21, lines 2-13 in order to provide the clarification requested by the examiner.

Claim 13 has been amended to delete "(M)". A disassociation constant is a molar ratio and, therefore, has no units. See the definition of "disassociation constant" from *The Concise Biotech Dictionary*, submitted herewith.

The rejection of claim 23 for indefiniteness is respectfully traversed to the extent that the examiner would require amendment to recite a step of removing the unbound marker prior to detection. While the undersigned does not have applicants' comments on this point, it appears to the undersigned from a reading of working examples 8, 13 and 17 that no such separation step is necessarily involved. Note the detection as colored lines on the substrate as described in working examples 8, 13 and 17, in the case of a positive, without a washing step.

Claim 23 has been amended to clarify that the complex captured by the solid phase conjugate is "an analyte complex comprising receptor I, receptor II and analyte A." See, for example, page 12, lines 26 and 27 of applicants' specification.

The rejection of claims 1, 9-11, 13, 14, 16, 18 and 20-23 for anticipation by Niemeyer et al is respectfully traversed. With respect to claim 1 and the claims dependent thereon, note that claim 1 has been amended to include the limitation of claim 8, reworded in light of Figs. 1, 4 and 6. Also note in Figs. 1, 4 and 6 that receptors I and II are discrete substances which, as taught in applicants' specification, bind together only through an analyte A, as shown for example in applicants' drawings. Accordingly, the rejection for anticipation, not applied to claim 8, is considered to be moot with respect to claim 1 as amended and the claims dependent thereon.

Regarding claim 23 and new claims 25 and 26 dependent thereon, note that claim 23 has been amended in a manner reflecting use of kits as shown in Figs. 1, 4 and 6 of the drawings. Nowhere do Niemeyer et al disclose or suggest contact of an analyte A with discrete reactants such as receptor I and receptor II, with subsequent capture by a solid phase conjugate.

The rejection of claims 4, 8 and 19 for obviousness over Niemeyer in view of Bayer et al is respectively traversed. Even if avidin is used as R1 or R2 of Niemeyer, with the plurality of biotinylated probes bound thereto, the teachings of Niemeyer so modified are not suggestive of a kit wherein a solid phase conjugate is stored separate from another reactant, much less another reactant in the nature of receptor II as defined.

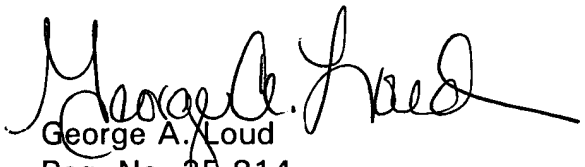
The rejection of claim 12 for obviousness over Niemeyer et al in view of Van Ness et al is respectfully traversed, substantially for the foregoing reasons. Even if the nucleotide ligands taught by Van Ness were used as the ligands of Niemeyer et al, any kit suggested by Niemeyer et al would not have separate reagents as in the kit as defined by claim 1 here, on which claim 12 depends. Further, claim 12 clearly requires that L1 and L2 have different sequences respectively complimentary to different portions of an oligonucleotide analyte A.

Finally, the rejection of claims 15 and 17 for obviousness over Niemeyer et al

in view of Billing-Medal et al, is traversed for the reason that these claims depend from claim 1 and Niemeyer et al, modified in the allegedly obvious manner in view of Billing-Medal et al, would still fail to meet the limitations of claim 1 for the reasons noted above.

In conclusion, it is respectfully requested that the examiner reconsider the rejections of record with a view toward allowance of the claims as amended.

Respectfully submitted,



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Dated: July 29, 2005

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The received stamp of the U.S. Patent Office Application Branch hereon acknowledges the filing of:

Application of: OKU et al 10/070161

Title: KITS AND METHODS FOR DETECTING OR MEASURING ANALYTES

Statement Pursuant to 37 CFR 1.821(f) Attached

No. of Pages of Specification: 48 No. of Claims: 25

No. of Sheets of Drawings: 4 Declaration XX Attached

Assignment XX Attached XX Sequence Listing PCT/IB/308 Attached

Preliminary Amendment XXX Attached

Information Disclosure Statement _____ Attached

Check in the amount of $ _____ Attached
Credit Card Payment Form for $1272.00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Application of:

OKU et al

Serial No.:

Filed: March 4, 2002

For: KITS AND METHODS FOR DETECTING AND MEASURING ANALYTES

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Please amend the captioned application as follows:

IN THE CLAIMS:

Please rewrite claims 4, 6, 8-17 and 20-22 as follows:

4. (Amended) The kit according to claim 1, wherein the substance R1 has a plurality of binding points with respect to the substance B1, and a plurality of the ligands L1 are bound to the substance R1 by the medium of the substance B1.

6. (Amended) The kit according to claim 1, wherein the substance R2 has a plurality of binding points with respect to the substance B2, and a plurality of the ligands L2 or ligands L3 are bound

to the substance R2 by the medium of the substance B2.

8. (Amended) The kit according to claim 1, wherein the solid phase conjugate is at least independent of the receptor II.

9. (Amended) The kit according to claim 1, wherein the analyte A having bivalent or higher binding capability is a substance selected from the group consisting of DNAs, RNAs, antigens, and antibodies.

10. (Amended) The kit according to claim 1, wherein the ligand L1, ligand L2 or ligand L3 is a substance selected from the group consisting of DNA, RNA, antigen, antibody, lectin, glycoprotein, and sugar.

11. (Amended) The kit according to claim 1, wherein the ligand L1 and the ligand L2 are the same substance.

12. (Amended) The kit according to claim 1, wherein the ligands L1 and L2 and the ligand L3 are substances having different sequences with one another.

13. (Amended) The kit according to claim 1, wherein the binding capability between the substance B1 and the substance R1 or between the substance B2 and the substance R2 is represented by a dissociation constant of from 10^{-8} to 10^{-16} (M).

14. (Amended) The kit according to claim 1, wherein the substance B1 and/or the substance B2 is biotin.

15. (Amended) The kit according to claim 1, wherein the substance B1 and/or the substance B2 is a substance selected from the group consisting of DNA, RNA, antigen, antibody, lectin, glycoprotein, and sugar.

16. (Amended) The kit according to claim 1, wherein the substance R1 and/or the substance R2 is a substance selected from the group consisting of streptavidin and avidin.

17. (Amended) The kit according to claim 1, wherein the substance R1 and/or the substance R2 is a substance selected from the group consisting of antigen, antibody, DNA, RNA, lectin, glycoprotein, and sugar.

20. (Amended) The kit according to claim 1, wherein the bond element B3 is bondable to the anti-bond element R3 by complementary binding of at least part of DNAs or RNAs.

21. (Amended) The kit according to claim 1, wherein the marker M is a substance selected from the group consisting of coloring dye, fluorescent dye, luminescent substance, metal colloid, latex, liposome, radioactive isotope, enzyme, DNA, and RNA.

22. (Amended) The kit according to claim 1, wherein the solid phase is a substance selected from the group consisting of polystyrene, nitrocellulose, nylon, cellulose, and glass.

Respectfully submitted,

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4. (Amended) The kit according to claim 1 [or 3], wherein the substance R1 has a plurality of binding points with respect to the substance B1, and a plurality of the ligands L1 are bound to the substance R1 by the medium of the substance B1.

6. (Amended) The kit according to claim 1 [or 2], wherein the substance R2 has a plurality of binding points with respect to the substance B2, and a plurality of the ligands L2 or ligands L3 are bound to the substance R2 by the medium of the substance B2.

8. (Amended) The kit according to claim 1 [any one of claims 1 to 3], wherein the solid phase conjugate is at least independent of the receptor II.

9. (Amended) The kit according to claim 1 [any one of claims 1 to 3], wherein the analyte A having bivalent or higher binding capability is a substance selected from the group consisting of DNAs, RNAs, antigens, and antibodies.

10. (Amended) The kit according to claim 1 [any one of claims 1 to 3], wherein the ligand L1, ligand L2 or ligand L3 is a substance selected from the group consisting of DNA, RNA, antigen, antibody, lectin, glycoprotein, and sugar.

11. (Amended) The kit according to claim 1 [or 3], wherein the ligand L1 and the ligand L2 are the same substance.

12. (Amended) The kit according to claim 1 [any one of claims 1 to 3], wherein the ligands L1 and L2 and the ligand L3 are substances having different sequences with one another.

13. (Amended) The kit according to claim 1 [any one of claims 1 to 3], wherein the binding capability between the substance B1 and the substance R1 or between the substance B2 and the substance R2 is represented by a dissociation constant of from 10^{-8} to 10^{-16} (M).

14. (Amended) The kit according to claim 1 [any one of claims 1 to 3], wherein the substance B1 and/or the substance B2 is biotin.

15. (Amended) The kit according to claim 1 [any one of claims 1 to 3], wherein the substance B1 and/or the substance B2 is a substance selected from the group consisting of DNA, RNA, antigen, antibody, lectin, glycoprotein, and sugar.

16. (Amended) The kit according to claim 1 [any one of claims 1 to 3], wherein the substance R1 and/or the substance R2 is a substance selected from the group consisting of streptavidin and avidin.

17. (Amended) The kit according to claim 1 [any one of claims 1 to 3], wherein the substance R1 and/or the substance R2 is a substance selected from the group consisting of antigen, antibody, DNA, RNA, lectin, glycoprotein, and sugar.

20. (Amended) The kit according to claim 1 [any one of claims 1 to 3], wherein the bond element B3 is bondable to the anti-bond element R3 by complementary binding of at least part of DNAs or RNAs.

21. (Amended) The kit according to claim 1 [any one of claims 1 to 3], wherein the marker M is a substance selected from the group consisting of coloring dye, fluorescent dye, luminescent substance, metal colloid, latex, liposome, radioactive isotope, enzyme, DNA, and RNA.

22. (Amended) The kit according to claim 1 [any one of claims 1 to 3], wherein the solid phase is a substance selected from the group consisting of polystyrene, nitrocellulose, nylon, cellulose, and glass.

The concise
Biotech Dictionary

A fre
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dissociation constant

A constant which quantifies the dissociation between two atoms, molecules, or larger particles. This constant is u equation K=[A][B]/[AB], where K is the dissociation constant, A and B are the two substances which are dissociat each other, and [] means "concentration of (in moles)."